488

OVERCOMING LOGISTICAL CHALLENGES IN PERFORMING INTERVENTIONAL CLINICAL TRIALS IN THE LONG-TERM FOLLOW-UP (LTFU) SETTING AFTER HEMATOPOIETIC CELL TRANSPLANTATION (HCT)

Dahlgren, C.J., Nguyen, H.-L., Choe, P., Boeckh, M. Fred Hutchinson Cancer Research Center, Seattle, WA.

Background: Conducting interventional clinical trials according to Good Clinical Practice (GCP) standards presents a formidable challenge in the LTFU period following HCT. Challenges include receiving blood specimens promptly from patients living in remote locations, gaining patient and provider commitment to regular lab testing and clinical assessments, and maintaining timely communication between providers and patients for clinical interventions. **Methods:** We evaluated logistical aspects of conducting an interventional clinical trial in the LTFU setting. Data from a multicenter, randomized placebo-controlled trial for prevention of late CMV complications were examined for: geographic distribution of patient location, feasibility of overnight shipment of specimens, and time to appropriate intervention following results. Clinical interventions consisted of (a) start of preemptive antiviral treatment for positive CMV quantitative PCR result (b) interruption of study drug administration and start of GCSF for any neutropenic episode defined by ANC <1.000/uL and (c) adjusting dose of study medication based on renal function. The study included 8 participating sites. All samples were analyzed at FHCRC, the central site. **Results:** 140 study participants were distributed over 112 cities and 36 states including Alaska. We received 3661 blood specimens (90% were collected at off-site locations). From the time each specimen was sent by overnight carrier, 85% were received by the central site in <24 hours, 9% were received between 24-48 hours, and 6% were received >48 hours. Treatment for CMV began after a median of 1 (range 0-7) day(s) after the PCR result was obtained. Upon report of the CMV PCR result to the provider, 26% of patients were treated on the same day, 37% within 1 day, 26% within 2 days, and 11% within 3 days. The median time from awareness of neutropenia to holding study drug was 0 (range 0-3) days; 81% of the patients held study drug on the same day of the result, 5% within 1 day, 11% within 2 days, and 3% within 3 days. Dose adjustment for renal function was implemented a median of 1 (range 0-2) day(s) upon obtaining the result. Of these renal adjustments, 2% occurred on the same day, 95% within 1 day, and 3% within 2 days. **Conclusions:** This study demonstrates that complex interventional randomized studies in the LTFU setting are feasible, even if most participants live in distant locations, and that therapeutic decisions can be made on a real-time basis.

489

QUALITY OF LIFE, SPIRITUAL WELL-BEING, AND SURVIVAL POST-HEMATOPOIETIC STEM CELL TRANSPLANTATION

Morris, M.E., Lynch, J.C., Bociek, G., Bierman, P.J., Vose, J.M., Armitage, J.O. University of Nebraska Medical Center, Omaha, NE.

Introduction: Quality of life (QOL) is an important outcome in the treatment of malignancy, including hematopoietic stem cell transplant (HSCT). QOL is conceptualized as multi-dimensional including physical, psychosocial, emotional, and spiritual well-being (SWB). **Purpose:** A longitudinal QOL study of post-HSCT recipients is being conducted at the University of Nebraska Medical Center (UNMC) to evaluate changes over time in QOL and to examine the relationship between patient, disease, and transplant characteristics and QOL. **Methods:** Participants complete the Medical Outcomes Survey SF-36, Functional Assessment of Cancer Therapy-Bone Marrow Transplant (FACT-BMT), and City of Hope (COH) Medical Center-BMT survivor questionnaires at baseline (pre-HSCT), day 100, and yearly post-HSCT. For each subscale, the sample was dichotomized as ≤80th percentile versus > 80th percentile of the baseline score, and clinical outcomes compared between the two groups. Results of the baseline COH SWB subscale, which includes questions regarding uncertainty, purpose, hope, and peace, are reported here. **Results:** Between September 2001 and June 2004, 172 participants received autologous HSCT for hematologic malignancy. Most (97%) were white, non-Hispanic, 55% were male, and the median age at transplant was 52 years (range 20-75). Median follow-up of surviving patients is 24 months (range 12-49) and 44 (25%) patients had progressed prior to analysis. The 3 year overall survival (OAS) rate for patients with high (>9.0) SWB was 93% compared to 79% for patients with lower SWB ($P = .05$, log rank test). However, baseline SWB was not a statistically significant predictor for event-free survival or relapse rate. No other COH subscale scores were significantly related to clinical outcome nor were any FACT subscale scores. **Discussion:** In this initial analysis, SWB at baseline is a significant predictor of OAS. Multivariate analysis is needed to determine if the impact of SWB can be explained by other patient characteristics such as co-morbidities or disease status at HSCT. **Implications:** Additional studies focusing on longitudinal spiritual assessment and intervention are needed to determine the long-term impact of SWB on QOL and survival.

490

DOES IT MATTER WHEN A PATIENT IS REFERRED FOR INITIAL CONSULT FOR BLOOD AND MARROW TRANSPLANT

Campbell, S.W., Dale, I.L., Lyons, P.A., Tate, D.F. University of Alabama at Birmingham (UAB) BMT Program, Birmingham, AL.

As data manager and bone marrow transplant coordinators at the University of Alabama at Birmingham (UAB) Bone marrow Transplant (BMT) Program, we are constantly seeking ways to help facilitate better patient outcomes. We, as a group, asked the question "Does it really matter when a patient is referred for blood and marrow transplant?" A retrospective analysis of 45 patients with hematological malignancies was done evaluating the appropriateness of the time frame from diagnosis of disease to the initial consultation with the BMT team and the overall outcomes based upon the recommendations from the National Comprehensive Cancer Network (NCCN) Guidelines. Of these 45 patients, 14 were deemed appropriate or early referrals, and 31 were defined as late for initial consultation with the BMT team during the 2004 calendar year. Fifty percent of the early referrals and 35% of the late referrals (18 patients total) went on to receive a HSCT. There were numerous reasons why the 27 patients failed to receive a HSCT, some of which include patient choice, disease relapse, and co-morbid conditions. Of the 18 patients who did receive a transplant, 11 of those patients are still alive and well today. Overall, based upon guidelines from the NCCN, our data supports early referral versus late referral.

491

WASHINGTON UNIVERSITY NURSING EXPERIENCE COORDINATING PATIENT CARE ON A PHASE III TRIAL EVALUATING AMD3100 (MOZOBIL™), A NOVEL DRUG FOR STEM CELL MOBILIZATION

Devine, H., Larson, S., Comer, H. Barnes-Jewish Hospital/Washington University Medical Center in St. Louis, St. Louis, MO.

AMD3100 (MOZOBIL™) is a novel agent which induces a rapid increase in the number of stem cells in peripheral blood. It appears to be safe and when combined with G-CSF may increase the yield of stem cells compared to G-CSF alone. The optimum mobilization occurs when the drug is scheduled the evening prior to apheresis, creating a number of potential logistical difficulties managing trials evaluating this agent. As we commenced accrual to a phase III placebo controlled study comparing G-CSF alone to its combination with MOZOBIL, we worked diligently to ensure there were no gaps in patient care. Patient teaching strategies included verbal instruction contrasting historical methods of stem cell mobilization with this novel procedure as well as printed BMT literature. All patients and their caregivers were offered involvement in a patient education class. The RN coordinator was instrumental in creating the patient's mobilization schema and further collaborating with the clinical research associate, apheresis department, stem cell laboratory, and the inpatient and outpatient treatment areas. Since our medical center does not have an after hours outpatient clinic, our patients received MOZOBIL/placebo on a designated inpatient unit. Challenges with this approach occurred when the inpatient unit was understaffed or had high acuity patients. Additionally, the inpatient RNs expressed concern regard-